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12	SAN FRANCISCO DIVISION				
13	In re LIDODERM ANTITRUST LITIGATION	MDL Docket No. 14-md-02521-WHO			
14	In re LIDODERM ANTITRUST LITIGATION				
15	This document relates to: Case No. 3:14-cv-02180-WHO	FIRST AMENDED COMPLAINT			
16					
17	GOVERNMENT EMPLOYEES HEALTH ASSOCIATION;	DEMAND FOR JURY TRIAL			
18	Plaintiff,				
19	v.				
20	ENDO PHARMACEUTICALS, INC.,				
21	TEIKOKU PHARMA USA, INC., TEIKOKU SEIYAKU CO., LTD., ACTAVIS, INC.,				
22	WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ANDA,				
23	INC., ANDA PHARMACEUTICALS, INC., and VALMED PHARMACEUTICALS, INC.;				
24	Defendants.				
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MDL Docket No. 14-md-02521-WHO Individual Case No. 3:14-cv-02180 - FIRST AMENDED COMPLAINT

Plaintiff Government Employees Health Association ("GEHA" or "Plaintiff"), files its First Amended Complaint ("Complaint") against Defendants Endo Pharmaceuticals, Inc., Teikoku Pharma USA, Inc., and Teikoku Seiyaku Co., Ltd. (collectively "Endo"), and Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed Pharmaceuticals, Inc. (collectively "Actavis") (all collectively "Defendants"), and alleges as follows based on: (a) first-hand knowledge; (b) the investigation of GEHA's undersigned counsel; and (c) information and belief:

I. NATURE OF THE ACTION

- 1. Endo sells Lidoderm, a brand name prescription drug. Lidoderm contains an amide-type local anesthetic agent. Lidoderm stabilizes neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses. Endo sells Lidoderm for use as a local anesthetic adhesive patch to relieve the pain associated with post-herpetic neuralgia, more commonly referred to as after-shingles pain.
- 2. Defendants have entered into an unlawful agreement that prevented less expensive, competitively-priced generic versions of Lidoderm from becoming available in the United States. But for Defendants' agreement, one or more generic versions of Lidoderm would have entered the market as early as August 23, 2012. The agreement has caused and continues to cause Plaintiff to pay inflated prices for this medicine during the relevant time period.
- 3. GEHA seeks damages comprised of the amounts Defendants' unlawful actions have caused it (and will continue to casue it) to overpay for Lidoderm and generic Lidoderm.
- 4. Since the United States Food and Drug Administration ("FDA") approved Lidoderm for manufacture and sale in the U.S. in 1999, Endo charged monopoly prices for, and earned monopoly profits from, Lidoderm. Endo had U.S. Lidoderm sales of approximately \$825 million in 2011, and \$950 million in 2012.
- 5. Generic drugs are much less expensive than their brand-name counterparts. GEHA would switch almost all of its purchases of monopoly-priced Lidoderm to the lower-priced generic version once the first generic entered the U.S. market, and again with even lower-priced generic versions after multiple generics become available.

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- Endo's patent relating to Lidoderm is U.S. Patent No. 5,827,529 (the "529 Patent"). The '529 Patent will expire on October 27, 2015. In December 2006, Endo, to protect its monopoly profits and prevent generic Lidoderm competition, filed a Citizen Petition with FDA raising questions about whether the FDA's proposed approval requirements for generic Lidoderm were sufficient to determine bioequivalence. The Citizen Petition raised a number of issues, including the appropriate safety and efficacy metrics, in establishing bioequivalence for a locally acting topical drug that produces a unique partial sensory block in patients suffering from Post Herpetic Neuralgia ("PHN"). In March 2012, Endo filed another Citizen Petition, this time highlighting the scientific and regulatory support for requiring generic manufacturers to conduct comparative clinical endpoint studies to demonstrate bioequivalence to locally acting topical products like Lidoderm. On August 23, 2012, Endo announced that FDA had denied Endo's Citizen Petitions concerning Lidoderm.
- 7. On November 13, 2009, Actavis sought FDA approval to sell a generic version of Lidoderm, and certified to the FDA that its generic did not infringe any valid patent held by Endo that covered Lidoderm. Shortly thereafter, Endo sued Actavis, alleging Actavis infringed Endo's '529 Patent. By so doing, Endo triggered an automatic stay of FDA's ability to approve Actavis' generic version of Lidoderm for up to 30 months.
- 8. To avoid (i) adjudication of the invalidity or non-infringement of the '529 Patent, or (ii) sale of generic Lidoderm upon FDA approval after the 30-month stay ended, either of which would have ended Endo's Lidoderm monopoly, in May 2012, Endo agreed to provide a Actavis wholesaler subsidiary with between \$96 and \$240 million in free product in exchange for Actavis' agreement to (a) discontinue its challenge to the '529 Patent; and (b) delay selling a generic version of Lidoderm until September 15, 2013. Actavis agreed not to resell the branded Lidoderm for less than Endo's monopoly prices.
- 9. Specifically, Endo agreed to provide Actavis \$12 million—in branded Lidoderm product, based on wholesale acquisition cost—in each month from January through August of 2013. Actavis in turn agreed to sell the branded Lidoderm product at the same supracompetitive price Endo sold it at. If the FDA did not approve Actavis' ANDA by December 31, 2013, Endo agreed to provide \$6.67 million in branded Lidoderm product to Actavis each month in 2014 that Actavis' ANDA had not

received FDA approval. If the approval was not achieved by December 31, 2014, Endo agreed to provide \$7.11 million monthly in branded Lidoderm product to Actavis.

- 10. The purpose and effect of this agreement was for the parties to allocate 100% of the market for Lidoderm to Endo through September 16, 2013, in consideration of Endo's reverse payments to its alleged patent infringer Actavis. This agreement is referred to herein as the "Reverse Payment Agreement" or the "Agreement."
- 11. Endo also agreed in the Reverse Payment Agreement not to launch an authorized generic to compete with Actavis' generic Lidoderm for seven and one-half months after Actavis belatedly launched its own generic. In exchange, during any exclusivity period enjoyed by Actavis, Actavis agreed to pay a 25% royalty on gross profit to Endo until another generic entered the market (including any authorized generic).
- 12. Zacks Investment Research, a website dedicated to providing professional investors with financial data and analysis, noted in a May 7, 2013 "Brokerage Research Digest" the significant importance to Endo of the Reverse Payment Agreement:

The settlement of the Lidoderm litigation with Actavis is a major positive for Endo. Actavis will launch its generic version in 2013 despite the FDA approval of its ANDA. The company [Endo] has too few new products to help it to bridge the gap after Lidoderm generics are launched in 2013. Lidoderm accounted for 31% of Endo's total revenue in 2012.

- 13. The Reverse Payment Agreement caused Actavis to delay marketing its generic version of Lidoderm until September 16, 2013, when Actavis announced it had "launched a generic version of Lidoderm (lidocaine topical patch 5%), as part of an exclusive settlement agreement with [Defendants] Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd." The division of monopoly profits between Endo and Actavis was mutually beneficial as free and unrestrained competition resulting in lower prices to consumers was foreclosed for a significant period of time.
- 14. Since January 2013, Endo has delivered to Actavis tens of millions of dollars in free product under the Reverse Payment Agreement, and in turn, delayed the availability of generic Lidoderm until September 16, 2013.

www.zacks.com/ZER/rd get pdf.php?r=ENDP.

- 15. For Endo, the deal with Actavis made sense, because the payments were virtually pure profit, and Actavis was happy to receive millions in free product without having to bear the costs of actual competition. If Actavis had turned down the deal and instead prosecuted its challenge to the '529 Patent successfully, it would likely have faced stiff competition: (a) from an authorized generic version of Lidoderm that Endo could have sold in competition with Actavis; and (b) after Actavis' 180 days of statutory exclusivity ended, from other generic entrants whose presence in the market would have driven prices of generic Lidoderm to commodity price levels. This competition would have significantly benefitted GEHA as it would have paid much lower prices for generic Lidoderm.
- 16. Defendants' unlawful Reverse Payment Agreement was designed to and did in fact: (i) delay and/or preclude the entry of less-expensive generic versions of lidocaine patch 5%; (ii) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time and lowered prices further; (iii) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products; (iv) permit Endo/Teikoku to maintain a monopoly for lidocaine patch 5%; (v) allocate 100% of the lidocaine patch 5% market in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Endo/Teikoku for up to thirteen months; and (vi) allocate 100% of generic lidocaine patch 5% sales in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Actavis for 7½ months.
- 17. As a direct and proximate result of Defendants' unlawful conduct alleged herein, GEHA has been injured in its business or property. GEHA asserts claims for compensatory damages (including, but not limited to overcharge damages in connection with purchases of certain quantities of (i) brand-name Lidoderm that would have been made at lower prices absent the Reverse Payment Agreement; (ii) brand-name Lidoderm that would have been substituted with purchases of generic Lidoderm absent the Reverse Payment Agreement; and (iii) generic Lidoderm made at inflated prices due to the Agreements), and/or treble damages for violations of the state laws enumerated below. These injuries is of the type the antitrust and consumer protection laws of the states, the District of Columbia, and Puerto Rico were designed to prevent and flows from that which makes Defendants' conduct unlawful.

II. JURISDICTION AND VENUE

- 18. This Court has jurisdiction over this action under 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000 and there is complete diversity of citizenship between Plaintiff and Defendants.
- 19. This Court has personal jurisdiction over Defendants because they are present in the United States, do business in the United States, have registered agents in the United States, and may be found in the United States.
- 20. Venue is appropriate within this district because Defendants transact business within this District, and their transactions regarding Lidoderm is carried out in this District. Venue, therefore, is appropriate within this District under 28 U.S.C. § 1391(b) and (c).

III. PARTIES

- 21. GEHA is a not-for-profit corporation providing health and dental plans to federal employees and retirees and their families through the Federal Employees Health Benefits Plan and the Federal Employees Dental and Vision Insurance Program. GEHA is the second-largest national health plan and the second-largest national dental plan serving federal employees, federal retirees and their families, providing benefits to nearly 1.5 million covered lives with federal employee members residing in all 50 states as well as the District of Columbia and Puerto Rico. GEHA is organized under the laws of Missouri and its principal place of business is located at 310 NE Mulberry Street, Lees Summit, MO 64086-5861.
- 22. GEHA purchased a significant amount of branded Lidoderm at monopoly prices during the relevant time period. After generic entry belatedly occurred in September 2013, GEHA's purchases of generic versions of Lidoderm also included, and will continue to include, overpayments resulting from the Defendants' illegal scheme until the market for generic Lidoderm stabilizes to a "steady state."
- 23. Defendant Endo Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. On May 23, 2012, Endo Pharmaceutical, Inc.'s shareholders approved a resolution to change the company's name to Endo Health Solutions, Inc. Endo Pharmaceuticals, Inc. is a pharmaceutical

Watson Pharmaceuticals, Inc. (now Actav
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company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain.

- 24. Defendant Teikoku Seiyaku Co., Ltd. is a Japanese corporation, with its principal place of business at 567 Sanbonmatsu Higashikagawa, Kagawa 769-2695, Japan. Teikoku Seiyaku is in the development, manufacture, and sale of medicated and medically related supplies, offering a range of hot sensation, and analgesic and anti-inflammatory plasters. Teikoku Seiyaku, through its subsidiaries, also engages in the research, development, and manufacture of pharmaceutical transdermal products, and the production and sale of medical adhesive products and external aqueous gel preparations, including Lidoderm.
- 25. Defendant Teikoku Pharma USA, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business at 1718 Ringwood Avenue, San Jose, California. Teikoku Pharma USA is a wholly-owned subsidiary of Teikoku Seiyaku Co., Ltd.
- 26. Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Actavis, Inc. is a wholly-owned subsidiary of Actavis plc., incorporated in Ireland on May 16, 2013 as a private limited company, and re-registered effective September 18, 2013 as a public limited company.
- 27. Defendant Watson Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Nevada, with its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. On October 31, 2012, Watson Pharmaceuticals, Inc. completed its acquisition of the Actavis Group. Watson Pharmaceutical, Inc.'s common stock was traded on the NYSE under the symbol "WPI" until close of trading on January 23, 2013, at which time Watson Pharmaceuticals, Inc. changed its corporate name to "Actavis, Inc." and changed its ticker symbol to "ACT." Actavis and Watson are referred to interchangeably throughout the Complaint.
- 28. Defendant Watson Laboratories, Inc. is a corporation organized under the laws of the State of Nevada, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway Parsippany, New Jersey 07054. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. (now Actavis, Inc.).

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- 29. Defendant Anda, Inc. is a corporation organized under the laws of the State of Florida, with its principal place of business at 2915 Weston Road, Weston, FL 33331. Anda, Inc. is a whollyowned subsidiary of Watson Pharmaceuticals, Inc. (now Actavis, Inc.).
- 30. Defendant Anda Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Florida, with its principal place of business at 6500 Adelaide Court, Groveport, OH 43125. Anda Pharmaceuticals, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. (now Actavis, Inc.).
- 31. Defendant Valmed Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York, with its principal place of business at 300 Alt Blvd., Grand Island, New York 14072. Valmed Pharmaceuticals, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. (now Actavis, Inc.).
- 32. The actions taken by Defendants are part of, and were taken in furtherance of, the unlawful scheme alleged. These actions were authorized, ordered, and/or done by the Defendants' officers, agents, employees, or other representatives while engaged in the management of the Defendants' affairs (or the affairs of Defendants' predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The Hatch-Waxman Act and FDA Approval Process

- 33. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 301, et seq.), a manufacturer that creates a new drug must obtain FDA approval to sell it by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents.
- 34. In 1984, Congress passed the Hatch-Waxman Act ("Hatch-Waxman"), which amended the Food, Drug and Cosmetics Act. Hatch-Waxman streamlined the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA to obtain FDA approval. Instead, Hatch-Waxman authorized an expedited FDA review whereby generic manufacturers file an Abbreviated New Drug Application ("ANDA"). An ANDA sponsor may rely on

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the safety and efficacy findings of the brand-name drug manufacturer in its NDA if the ANDA demonstrates its proposed generic drug is "bioequivalent" to the corresponding brand-name drug. Bioequivalence requires delivery of the same active ingredient into the body at the same rate as the brand.

- 35. Hatch-Waxman also streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with the ability to easily obtain what is essentially a preliminary injunction, in the form of a stay of up to 30 months of FDA approval of generic manufacturer's ANDAs.
- 36. When FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to information supplied to FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).
- 37. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patent listed in the Orange Book claiming the brand-name drug. A generic manufacturer's ANDA must contain one of four certifications:
 - a. that no patent for the brand-name drug has been filed with FDA (a "Paragraph I Certification"):
 - b. that the patent for the brand-name drug has expired (a "Paragraph II Certification");
 - that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
 - d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").
- 21 U.S.C. § 355(g)(2)(A)(vii).
- 38. Alternatively, with a method-of-use patent, an ANDA may assert that the patent is inapplicable to the use (the "indication") for which the drug product will be marketed.
- 39. When a generic manufacturer files a Paragraph IV Certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, it must promptly give notice of its

certification to both the brand manufacturer and the patent owner. If either files a patent infringement lawsuit against the ANDA filer within 45 days of receiving the Paragraph IV certification, FDA may not grant final approval to the ANDA until the earlier of (a) 30 months or (b) a court ruling that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

- 40. During the 30-month stay, FDA may grant "tentative approval" to an ANDA applicant if FDA determines that the ANDA would otherwise qualify for final approval, but cannot authorize the generic manufacturer to market its drug before the 30-month stay expires or a court rules on invalidity and infringement.
- 41. Congress created incentives for generic drug manufacturers to challenge weak patents. Hatch-Waxman granted the first filed sponsor of a substantially complete Paragraph IV ANDA a 180-day period of market exclusivity. During the 180-day exclusivity period (measured from the first commercial marketing of the generic), the first filer enjoys temporary freedom from competition from other generic versions of the drug, and can sell the generic for a higher price than when multiple generics enter the market. The brand name manufacturer may, however, market its own generic equivalent of the brand name drug (known as an "authorized generic") during the 180-day period.
- 42. The first-filed generic manufacturer can forfeit its right to the 180-day period of exclusivity. This can occur, for example, when the first-filer fails to receive tentative approval of its ANDA from FDA within 30 months of filing the ANDA.
- 43. Once the FDA approves a generic version of a branded drug is approved by FDA, it receives an "AB" rating. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of the price differentials, and other structural features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease much more significantly because of price competition among the generic manufacturers, and because the shift of sales volume from the brand-name drug to the corresponding generics is so dramatic. The FTC estimates that the price for a generic version of a drug will drop more than 90 percent below the price of the branded product when multiple generics are on the market. *See, e.g.*,

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http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlementspharmaceutical-industry-how-congress-can-stop-anticompetitive-conductprotect/090623payfordelayspeech.pdf.

- 44. An AB rating is critical to a generic manufacturer because, under Hatch-Waxman and most state law (i.e., Drug Product Selection laws, or "DPS laws"), pharmacists may (and, in most states, must) substitute only an AB-rated generic for the brand-name drug, without seeking or obtaining permission from the prescribing doctor. Both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.
- 45. Generic competition enables purchasers to buy generic versions of brand-name drugs at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing a substantial portion of its sales. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including the tactics alleged, to delay the introduction of ABrated generic competition into the market.

В. The Economic Model of Prescription Drug Purchases and Sales

- 46. A prescription drug is typically sold in capsule, tablet or, in this case, transdermal patch form through a distribution chain of manufacturers to wholesalers to retail pharmacies, which deliver the product to patients with prescriptions. The drug passes in unaltered form through the chain from manufacturer to patient. This is the case with Lidoderm.
- 47. Although a minority of patients do not have third party payer pharmacy benefits, in the overwhelming majority of the cases, the "end payer" for a prescription drug is a dual payer comprising a patient and his third party payer ("TPP").
- 48. Manufacturers of brand name prescription drugs sell the drug in final form, ready for consumption, to wholesalers and large pharmacies at a discount to the manufacturer's published price.

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Wholesalers in turn typically sell the branded drug to retail pharmacies at a slightly smaller discount from the published price, thereby achieving a small percentage markup.

- 49. Virtually all United States pharmacies have dispensing contracts with TPPs. Under these contracts, for drugs dispensed to members of TPP plans, pharmacies typically charge the TPP and consumer end payer a retail price based on a percentage of the published price, plus a dispensing fee of \$1.00–\$5.00 per prescription. The pharmacies collect a co-payment from the member, which typically ranges from \$10–\$50 (with a lower co-payment for generic drugs), and the balance from the TPP.
- 50. After AB-rated generic bioequivalents of a branded drug become readily available, TPPs reduce the amount they will pay to the pharmacy to a price based upon the lower price of the available generic.
- 51. For some the TPP's members either accept the lower-priced generic (which generally also reduces the amount of his or her co-payment) or else pay the difference between what the TPP would pay for the generic versus the branded drug.
- 52. Some health benefit plan members have a dual-payment relation which, instead of a flat co-payment by the consumer, comprises the member paying a percentage of the prescription cost and the TPP paying the balance.
- For the minority of consumers without a TPP co-payer, the entire price of prescription 53. drug is paid by such consumers.

V. **FACTUAL ALLEGATIONS**

A. **Background**

Approval of Brand Lidoderm and its Purported Patent Protection 1.

54. Lidoderm is a prescription lidocaine-containing patch approved to treat pain associated with post-herpetic neuralgia. The active ingredient in Lidoderm is 5% lidocaine. While other drugs are available to treat the same or similar medical conditions, they are not AB-rated to Lidoderm, cannot be automatically substituted for Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Lidoderm, and are not economic substitutes for, nor reasonably interchangeable with, Lidoderm.

a. Initial Approval of Lidoderm

- 55. On March 19, 1999, the FDA approved NDA 20-612, submitted by Hind Health Care, Inc. ("Hind"), allowing Hind to market an adhesive patch containing 5% lidocaine under the brand name Lidoderm. Lidoderm was awarded Orphan Drug Exclusivity status by the FDA, meaning that no generic competitor could get FDA approval to market a generic Lidoderm product until March 2006.
- 56. In 1998, Hind granted Endo the exclusive right to market and distribute Lidoderm in the United States. Hind subsequently transferred full ownership of and responsibility for the Lidoderm NDA to Teikoku, effective June 1, 1999. Teikoku then granted Endo the exclusive right to market and distribute the Lidoderm patch in the United States under Teikoku's NDA, and Endo launched Lidoderm in the United States in 1999.

b. Endo/Teikoku's Acquisition of Lidoderm Patents

- 57. Endo/Teikoku owned or obtained assignments of or licenses to a number of patents associated with Lidoderm. Teikoku listed several patents in the Orange Book as covering Lidoderm. As of January 2010 (after Actavis had filed ANDA No. 20-675, the first filed Lidoderm ANDA), Teikoku had three patents listed in the Orange Book.
- 58. The first was U.S. Patent No. 5,411,738 (the "738 Patent"), which is a method of use patent for treating certain types of pain with lidocaine using a topical delivery mechanism and a gel formulation of lidocaine. The second was U.S. Patent No. 5,601,838 ("the '838 Patent"), which is a method of use patent for treating certain types of pain with lidocaine. Both the '738 and '838 Patents (the "Hind Patents") were assigned to Hind, and both expired on May 2, 2012.
- 59. The third patent that Teikoku listed in the Orange Book as covering Lidoderm was U.S. Patent No. 5,827,529 (the "529 Patent"), which is a formulation patent for a lidocaine patch. This patent was assigned to Teikoku, and is set to expire on October 17, 2015. Endo is the exclusive licensee of the '529 Patent.
- 60. The '529 Patent, titled "External Preparation for Application to the Skin Containing Lidocaine," issued on October 27, 1998, from an application filed on June 10, 1994. That application was a continuation of an application filed on March 30, 1992.

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- 61. The '529 Patent claims foreign priority to Japanese Application No. 3-067353, filed March 30, 1991.
- 62. The '529 Patent contains six claims directed generally to a hydrogel transdermal patch containing the active ingredient lidocaine and inactive ingredients or excipients.
- 63. Claim 1 of the '529 Patent claims a patch comprising "a drug-retaining layer placed on a support," in which the drug-retaining layer comprises an "adhesive gel base and 1 to 10% by weight of lidocaine." The claimed "adhesive gel base" consists of three components within specific percentage weight ranges: (i) "0.5 to 50% by weight of a water-soluble high molecular weight substance"; (ii) "30 to 70% by weight of water"; and (iii) "1 to 70% by weight of a water-retaining agent."

c. Endo/Teikoku Try to Evergreen Lidoderm's Patent Protection

- 64. Endo subsequently obtained additional patents from LecTec Corporation ("LecTec") that it and Teikoku claim cover Lidoderm. In July 2008, LecTec had filed patent infringement litigation against Endo and other manufacturers of medicinal patch products in the United States District Court for the Eastern District of Texas (the "LecTec Litigation") over U.S. Patent No. 5,536,263 (the "263 Patent"), and U.S. Patent No. 5,741,510 (the "'510 patent"), both of which are patents for a medicinal adhesive patch. These patents both expired on March 30, 2014.
- 65. Endo settled the LecTec litigation in November 2009, paying LecTec \$23 million in exchange for exclusive licenses to the '263 and the '510 Patents for use in the field of prescription pain medications and treatment.
- 66. Almost a year later, in October 2010, Endo granted Teikoku a sublicense under the '510 Patent to make and sell prescription pain medications that contain 5% lidocaine in patch dosage form, including Lidoderm.
- 67. In November 2010, Teikoku submitted the '510 patent to FDA for listing in the Orange Book with respect to Lidoderm.
- 68. As of January 2011, Endo/Teikoku had four patents listed in the Orange Book related to Lidoderm: the two Hind Patents (which expired in May 2012), the '529 Patent, and the '510 Patent.
- 69. In or about May 2011, in exchange for \$2 million, Endo acquired from LecTec full title to the '263 Patent, the '510 Patent and three other patents. The three other patents were U.S. Patent No.

6,096,333 (the "'333 Patent"), (ii) U.S. Patent No. 6,096,334 (the "'334 Patent"); and (iii) U.S. Patent No. 6,361,790 (the "'790 Patent") (collectively with the '263 and the '510 Patents, "the Rolf Patents," named for one of the inventors). These three patents all cover methods of formulating a medicinal adhesive patch and expired on March 30, 2014. Other than the '510 Patent, none of the Rolf Patents was listed in the Orange Book with respect to Lidoderm.

2. Actavis' ANDA Threatens Endo/Teikoku's Weak Patents

- 70. On November 13, 2009, Actavis submitted ANDA No. 20-675 to FDA, seeking to market a generic version of Lidoderm. On January 14, 2010, Actavis notified Teikoku of its ANDA filing.
- 71. Actavis' notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Lidoderm product would not infringe any claim of the '529 Patent, and/or that the '529 Patent was invalid and/or unenforceable.
- 72. Actavis was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to Lidoderm, potentially entitling it to a six-month exclusivity period, free from competition from any other ANDA-filing generic company. This exclusivity, however, would not have protected Actavis from competition from an authorized generic version of Lidoderm.
- 73. Actavis did not submit Paragraph IV certifications as to the Hind Patents, which were to expire on May 2, 2012. As a result, FDA could not approve Actavis' ANDA for generic Lidoderm until the Hind Patents expired on May 2, 2012.
- 74. Actavis made no certification to any of the Rolf Patents because the Rolf Patents were not listed in the Orange Book until November 2010, a year after Actavis filed its ANDA. Actavis did not—and, under 21 C.F.R. § 314.94(a)(12)(vi), was not required to—file an amended Paragraph IV certification as to the '510 Patent.
- 75. The FDA granted final approval to Actavis' ANDA on August 23, 2012, but Actavis did not launch its approved generic Lidoderm product until September 16, 2013, because of the unlawful Reverse Payment Agreement with Endo/Teikoku. No patents asserted, or capable of being asserted, by Endo/Teikoku would or could have prevented Actavis from launching its approved generic Lidoderm product.

3. Endo and Teikoku Scramble to Protect Their Lidoderm Monopoly

- 76. On February 19, 2010, Endo/Teikoku sued Actavis in the United States District Court for the District of Delaware (*Endo Pharm. Inc., et al., v. Watson Labs., Inc.*, Civil Action No. 10-cv-00138-GMS), alleging that Actavis' generic Lidoderm infringed the '529 Patent (the "'529 Litigation"). As a result of the filing of the '529 Litigation, a 30-month Hatch-Waxman stay of FDA approval applied to Actavis' ANDA, which precluded FDA from approving Actavis' ANDA until the earlier of (i) the date that stay expired in mid-July of 2012, or (ii) the date of entry of a final judgment that the '529 Patent was invalid, unenforceable, and/or not infringed.
- 77. On March 4, 2010, Actavis counterclaimed, seeking a declaratory judgment that: (1) the '529 Patent was invalid; (2) Actavis' proposed generic product did not infringe the '529 Patent; and (3) the '529 Patent was unenforceable for inequitable conduct.
- 78. As the '529 Litigation headed to trial, on June 29, 2011 Endo filed a second patent suit against Actavis, this time using the Rolf Patents, *Endo Pharm. Inc. v. Watson Labs., Inc.*, Civil Action No. 11-cv-00575-GMS) (D. Del.) (the "Rolf Patent Litigation"), alleging that Actavis' generic Lidoderm product would infringe three of the Rolf Patents (the '333 Patent, the '334 Patent, and the '510 Patent). Only the '510 Patent had been listed in the Orange Book. Because the Rolf Patents had not been listed in the Orange Book when Actavis filed its ANDA, the Rolf Patent Litigation did not result in a 30-month Hatch-Waxman stay.

a. The '529 Litigation Exposed the Weakness of Endo/Teikoku's '529 Patent

79. At the June 27, 2011 *Markman* hearing in the '529 Litigation, Judge Sleet rejected Endo's claim construction position, strengthening Actavis' defense to Endo/Teikoku's infringement claims. The '529 Litigation then proceeded to a bench trial in February 2012, in which Actavis presented compelling evidence of the invalidity of the '529 patent, as well as strong evidence that Actavis' generic did not infringe the patent. The evidence at trial was overwhelmingly in favor of Actavis, exposing the '529 Patent to a determination that it was invalid or unenforceable and that the patent did not cover either the brand product or Actavis' generic product.

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(1) The '529 Patent Was Invalid

- 80. The evidence developed during the '529 Litigation revealed that the same hydrogel transdermal patch technology claimed in the '529 Patent had previously been disclosed in multiple instances of prior art that were not disclosed to the patent examiner, but were well known to Endo/Teikoku (the "Teikoku Prior Art"). The Teikoku Prior Art disclosed a hydrogel transdermal patch formulation substantially similar to that claimed in the '529 Patent.
- 81. The Teikoku Prior Art disclosed an "adhesive gel base" consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a water-retaining agent, all of which fall within the percentage ranges claimed in the '529 Patent. Each shares at least one inventor with the '529 Patent, and also shares the same applicant, prosecuting attorneys, or assignee with the '529 Patent.
- 82. During the prosecution of the '529 Patent, the United States Patent and Trademark Office ("PTO") rejected the patent four times, noting that because lidocaine was conventionally used in transdermal patches, it would have been obvious to place lidocaine into available prior art patches. The applicants consistently distinguished other prior art patches cited by the PTO examiner, arguing that the patch in the '529 Patent was "unique." The applicants never disclosed the Teikoku Prior Art to the PTO, or a prior art patent with the same elements as the '529 Patent, which would have showed that the patch technology in the '529 Patent was not unique, and in fact had been previously patented. The PTO never cited the Teikoku Prior Art.
- 83. Each of these prior art references is prior art to the '529 Patent because each was publicly available and accessible more than one year before the March 30, 1991 priority date of the '529 Patent. Each of the prior art references predates the priority date of the '529 Patent by over a year, and thus invalidates the '529 Patent. The '529 Patent was not capable of preventing Actavis from launching its approved generic Lidoderm product.

(2) The '529 Patent Was Not Infringed

84. In addition to being invalid, the '529 Patent did not cover Lidoderm and was not infringed by Actavis' generic equivalent. The patch formulation disclosed in the '529 Patent included a water-soluble high-molecular-weight substance, water, and a water-retaining agent. The water-soluble high-molecular-weight substance and the water-retaining agent must be from the groups listed in the

patent. The groups listed in the '529 Patent are known as Markush groups. "A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." *Endo Pharm. Inc.*, *et al.*, *v. Watson Labs.*, *Inc.*, slip op. at 1 n.1, No. 10-138 (GMS) (D. Del. June 27, 2011) (*quoting Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

- 85. In the '529 Patent, the first Markush group related to "a water-soluble high molecular weight substance selected from the group consisting of gelatin, starch, agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin, methylcellulose, methylcellulose sodium, carboxymethylcellulose, carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl pyrrolidone, copolymer of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and locust bean gum."
- 86. The second Markush group related to "a water-retaining agent selected from the group consisting of ethylene glycol, diethylene glycol, polyethylene glycol, glycerin, sorbitol, martitol, propylene glycol and 1,3-butylene glycol."
- 87. As the District Court held in its *Markman* decision construing those two patent terms, Federal Circuit precedent from 2003 clearly established that both of the relevant Markush groups in the '529 Patent were limited to one and only one of the listed alternatives. *Endo Pharm. Inc., et al., v. Watson Lab., Inc.*, slip op. at 1 n.1-2. Under Federal Circuit precedent, the patent must be interpreted to cover a product which contains only *one* of the substances from each of the two Markush groups.
- 88. Actavis' generic Lidoderm product contained at least *five* water-soluble high-molecular-weight substances, and *three* water-retaining agents. (So does Lidoderm.) Thus, it did not infringe the '529 Patent because it contained more than one substance from each Markush group. As a result, Actavis' generic Lidoderm product did not infringe the '529 Patent. The '529 Patent was not capable of preventing Actavis from launching its approved generic Lidoderm product.

b. The Rolf Patent Litigation

89. The Rolf Patents afforded Endo/Teikoku no basis to prevent Actavis from launching its approved generic Lidoderm product, either. Endo/Teikoku sued Actavis only on some of the Rolf Patents (the '510, '333, and '334 Patents). Actavis had raised defenses and counterclaims alleging

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those patents were invalid and/or unenforceable and that its product did not infringe them. Endo/Teikoku did not even sue Actavis on the '263 Patent. The Rolf Patent Litigation barely proceeded past the pleading stage. The Rolf patents posed no reasonable risk to Actavis of patent infringement liability.

- 90. Of the Rolf Patents, only the '510 Patent had been asserted by its previous owner, LecTec, against Endo with respect to its Lidoderm product in the LecTec Litigation in 2008. As Endo/Teikoku learned from the LecTec Litigation, the '510 Patent was subject to a strong invalidity challenge. The '510 Patent was invalid as obvious in view of prior art references that were not submitted to the PTO during the prosecution of the '510 Patent. Actavis, too, was aware of the infirmities of the '510 Patent from the publicly filed pleadings in the LecTec Litigation. The '510 Patent was incapable of preventing Actavis from launching its approved generic Lidoderm product.
- The '333 and '334 Patents were also not infringed by Actavis. Indeed, during the 91. LecTec litigation, LecTec had not even sued Endo for infringement of the '333 and '334 Patents with respect to Lidoderm. When Endo ultimately settled the LecTec Litigation in November 2009, it obtained licenses only for the '263 and '510 Patents, further evidence that licenses to the '333 and '334 Patents were immaterial to the use, manufacture, or sale of Lidoderm. Actavis' generic patch, a copy of the Endo patch, similarly would not infringe the '333 and '334 Patents.
- 92. Indeed, Endo did not attempt to obtain the rights to the '333 and '334 Patents until May 2011, when it bought the rights to all of the Rolf Patents from LecTec for just \$2 million, still further evidence that those patents were incapable of preventing Actavis from launching its approved generic Lidoderm product. None of the Rolf Patents was capable of preventing Actavis from launching its approved generic Lidoderm product.

В. Actavis and Endo's Illegal Scheme to Delay Generic Competition

- 93. There are approximately 1,000,000 shingles cases in the U.S. annually. PHN, treatable with Lidoderm, is the most common shingles complication, affecting roughly 13% of people over age 60 that have shingles. PHN typically lasts for several weeks or months, but may last for years.
- 94. In 2012, Endo sold close to \$1.1 billion worth of Lidoderm, accounting for almost 31% of Endo Pharmaceuticals, Inc.'s sales revenue that year. During this period, Endo possessed the market

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power to charge high prices on Lidoderm without losing customers, and it used its market power repeatedly, raising prices well above its flat costs, while simultaneously increasing its sales volume.

- 95. Had Actavis succeeded in the '529 Patent Litigation, it would have been able to sell its lower-priced generic version of Lidoderm. It would also have enabled competition from other generic manufacturers (including, but not limited to, a potential authorized generic sold by Endo). Because generic versions of brand-name drugs tend to be much less expensive than their brand-name counterparts, and because purchasers usually switch quickly from a brand to a generic once the generic becomes available, Endo's monopoly profits would have quickly declined once Actavis or other lower-priced generic versions of the product entered the market.
- 96. To preserve and protect Lidoderm from generic competition, on May 28, 2012 Endo entered into the agreement with Actavis settling the two patent cases while a decision from the court in the '529 Litigation was still pending. The Reverse Payment Agreement ended the '529 Litigation and the Rolf Patent Litigation, and obviated the need for Judge Sleet to render decisions on the validity, enforceability, and infringement of the patents Endo/Teikoku had asserted against Actavis.
- 97. Under the Agreement, Actavis agreed to delay launching its generic Lidoderm product until a "Start Date" of September 15, 2013 unless before that date another generic product launched (a virtual impossibility) or Actavis faced forfeiture of its 180-day exclusivity for failing to go to market (also a virtual impossibility). The Agreement specifically provides:

. . . Watson [now Actavis] . . . agrees . . . that, prior to the Start Date, it . . . shall not . . . market . . . any of Watson's Generic Product.

"Start Date" means the earliest of: (i) September 15, 2013; (ii) the date of Launch of any Generic Product other than Watson's Generic Product; or (iii) the last day before Watson would forfeit its 180-day generic drug exclusivity with respect to Watson's Generic Product due to the operation of 21 U.S.C. 355(j)(5)(D)(ii) as a result of a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(I).

98. As one *quid pro quo* for Actavis' promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo/Teikoku promised to share their monopoly profits with Actavis by paying Actavis at least \$96 million (in the form of brand Lidoderm provided by Endo/Teikoku at no cost to Actavis) at the rate of \$12 million per month from January 1 to August 1, 2013. Actavis was free to sell the brand Lidoderm product and retain the full proceeds of those sales. This payment was

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no different than if Endo/Teikoku had made those sales themselves and paid Actavis the resulting \$96 million in cash.

- 99. Endo/Teikoku also agreed to make additional payments to Actavis if Actavis did not receive FDA approval for its generic Lidoderm product by January 1, 2014, as well as additional payments if Actavis did not receive approval by January 1, 2015. Actavis received final FDA approval on August 23, 2012, within three (3) months of Defendants' execution of the Reverse Payment Agreement.
- 100. As the Agreement expressly provided, this \$96 million payment from Endo/Teikoku to Actavis was made to induce Actavis to abandon its challenge to Endo/Teikoku's patents:

Endo/Teikoku and Watson agree that the Brand Product provided by Endo/Teikoku to Watson's Wholesaler Affiliate hereunder is a good-faith, bargained-for resolution of the claims at issue in the Litigation. The Brand Product provided hereunder is not contingent on any past or future purchase of any product from Endo or Teikoku by Watson or any of its Affiliates.

- 101. Through the Agreement, Defendants ensured that Actavis' Lidoderm sales would not result in price competition—Actavis promised to sell brand Lidoderm at the same supracompetitive prices at which Endo had been selling it. Actavis maintained the supracompetitive prices for brand Lidoderm throughout the term of the Agreement, generating revenues of approximately \$96 million from those sales. Actavis' sales of branded Lidoderm did not increase output, reduce price, or increase consumer choice; it merely substituted Actavis for Endo/Teikoku as the seller of \$96 million worth of branded Lidoderm, solely to pay Actavis for delaying market entry of its less-expensive generic Lidoderm. The agreement not to price Lidoderm independently was, by itself, a naked price fixing agreement.
- 102. As a second payment in exchange for Actavis' promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo/Teikoku promised to delay launching an authorized generic version of Lidoderm for 7½ months after Actavis' belated launch of generic Lidoderm, unless another ANDA filer entered the market during that time (a virtual impossibility that, in fact, did not occur).
- 103. Endo/Teikoku were otherwise ready, willing, and able to launch an authorized generic version of Lidoderm simultaneously with Actavis' launch. As early as April 2007, Endo and Teikoku

had specifically agreed that Endo would be the exclusive licensee for authorized generic Lidoderm. As shown below, this no-authorized-generic promise effectuated a payment from Endo/Teikoku to Actavis of at least \$170 million or more.

104. Endo/Teikoku's agreement not to launch an authorized generic meant that Endo/Teikoku would cede those sales to Actavis, and Actavis would therefore be the sole generic on the market for 7½ months. This would allow Actavis to obtain 100% of generic Lidoderm sales for 7½ months (instead of just 50% if Endo/Teikoku had launched an authorized generic) and additionally permitted Actavis to avoid the inter-generic price competition an authorized generic necessarily creates and thereby maintain an artificially-inflated supracompetitive generic price for those doubled generic sales. These doubled revenues and profits were at the expense of Plaintiff, and competition in general. The Agreement (which refers to an authorized generic by the acronym "AG") provides:

<u>License</u>. Subject to the terms and conditions of this Agreement, Endo/Teikoku hereby grant to Watson a non-exclusive (other than pursuant to Section 2(b)), royalty-bearing, non-transferable (other than pursuant to Section 21) and non-sublicensable (other than pursuant to Section 2(c)) license to the Licensed Patents to make, have made, import, use, sell, and offer for sale Watson's Generic product in the Territory solely during the License Term.

AG Product. The license granted pursuant to Section 2(a) shall be partially exclusive for a period of time in that Endo/Teikoku and their respective Affiliates shall not market or sell a Generic Product, or authorize or license a Third Party to market or sell and AG Product at any time before the earlier of (i) seven and a half (7.5) months from the Start Date, and (ii) the Launch of any Third Party Generic Product in the Territory.

105. Endo/Teikoku's agreement not to launch an authorized generic for 7½ months allowed Actavis to double its generic sales *and* charge higher prices for its generic during that time (because it faced no competition from an authorized generic), and had a cash value to Actavis of \$170 million or more. Endo/Teikoku's no-authorized-generic promise is little different than if Endo/Teikoku actually did launch an authorized generic alongside Actavis during the first 7½ months that Actavis marketed generic Lidoderm, and simply handed the proceeds from those sales over to Actavis in cash. (Though Endo/Teikoku would have to give Actavis additional monies on top of those revenues, to make up for the higher price Actavis' generic Lidoderm would have been able to command because it was free from price competition from Endo/Teikoku's authorized generic).

VI. ANTICOMPETITIVE EFFECT

111. The Reverse Payment Agreement has enabled the Defendants to: (a) delay the entry of less expensive generic versions of Lidoderm in the United States; (a) fix, raise, maintain, or stabilize the

106. Absent the Reverse Payment Agreement, and Endo/Teikoku's promise not to launch an authorized generic contained therein, Endo/Teikoku would have launched an authorized generic simultaneously with Actavis' entry, which would have resulted in lower prices to Plaintiff, and cut Actavis' revenues and profits from selling generic Lidoderm by half.

- 107. In fact, at their first opportunity following the expiration of the no-authorized-generic promise, Endo/Teikoku immediately launched an authorized generic.
- 108. The no-authorized-generic promise was a very large payment to Actavis. Using a conservative approach that relies upon the revenue numbers that Endo reported in its filings with the Securities and Exchange Commission as an input for the annual revenue from Lidoderm, and valued as of the time the Reverse Payment Agreement was entered, the no-authorized-generic promise constituted a payment of at least \$170 million or more from Endo/Teikoku to Actavis. This figure is estimated based upon known dynamics of the pharmaceutical industry and publicly-available information.
- 109. GEHA estimates that the total payment flowing from Endo/Teikoku to Actavis, including both the \$96 million in free goods and Endo/Teikoku's promise to delay launching an authorized generic version of Lidoderm for 7½ months had a cash value in the hundreds of millions of dollars. The reverse payments are far greater than Endo/Teikoku's avoided litigation costs, and were not for services to be provided by Actavis to Endo/Teikoku. Rather, the reverse payments were made in order to induce Actavis to stay out of the lidocaine patch 5% market until September of 2013 and to allow Defendants to share monopoly profits.
- 110. Absent Endo/Teikoku's unlawful reverse payments to Actavis, any agreement settling the patent litigation would have resulted in much less delay of Actavis' generic entry than with the payments. But for the reverse payments, Actavis would have launched much earlier than September 2013, either under an agreement without any reverse payments, or at risk after final approval. And, in either circumstance, Actavis' entry would have been immediately met with Endo/Teikoku's authorized generic.

price of Lidoderm and its AB rated bioequivalents; and (c) allocate among them, and share the profits from, the U.S. market for Lidoderm and its AB rated bioequivalents during the relevant time period.

- 112. But for the continuing illegal agreements between Actavis and Endo (which included financial inducements to delay the launch of less expensive generic versions of Lidoderm), Actavis would have sold a less expensive AB-rated generic version of Lidoderm on or after August 23, 2012, but prior to September 16, 2013. Other ANDA-based generic versions of Lidoderm would have followed into the market 180 days later and/or Endo would have launched an authorized generic product contemporaneously with the first generic launch.
- 113. Defendants' unlawful concerted action delayed the sale of generic Lidoderm in the United States, causing GEHA to overpay for Lidoderm at artificially inflated, supra-competitive prices.

VII. MARKET POWER AND RELEVANT MARKET

- 114. At all relevant times, Endo had substantial market power (*i.e.*, monopoly power) with respect to Lidoderm because it had the power to maintain the price of the drug it sold as Lidoderm at supra competitive levels without losing so many sales as to make the supra competitive price unprofitable.
- 115. A small, but significant, non-transitory price increase above the competitive level for Lidoderm by Endo would not have caused a loss of sales sufficient to make the price increase unprofitable.
- 116. At competitive price levels, Lidoderm does not exhibit significant, positive crosselasticity of demand with respect to price with any product other than AB-rated generic versions of Lidoderm.
- 117. The differing efficacy, safety, and side effect profiles of different treatments play a critical role in doctors' selection of the most appropriate treatment for a particular patient. There are no interchangeable drug products that are available to prescribing physicians for the indications for Lidoderm. FDA does not consider such products to be bioequivalent or substitutes.
- 118. Endo needed to control only Lidoderm and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lidoderm profitably at supra competitive prices. Only the market entry of a competing, AB-rated generic version of Lidoderm would render Endo unable to

profitably maintain supra competitive prices for Lidoderm. Defendants had, and exercised, the power to exclude and restrict competition for Lidoderm and AB-rated bioequivalents.

- 119. Endo, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market as a result of patent and other FDA regulatory protections, creating high and expensive barriers to entry and expansion from competitors.
- 120. To the extent that Plaintiff is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiff alleges that the relevant market is the market for Lidoderm (i.e., Lidoderm and its AB-rated generic equivalents). During the period relevant to this case, Endo has been able to profitably maintain the price of Lidoderm well above competitive levels.
- 121. The relevant geographic market is the United States and its territories. At all relevant times prior to generic entry, Endo's market share in the relevant market was 100%, demonstrating market power.

VIII. ANTITRUST INJURY

- 122. GEHA has spent a significant amount on purchases of Lidoderm therapy during the relevant time period. Because of the Defendants' illegal conduct, GEHA was compelled to pay artificially inflated prices for Lidoderm. Those prices were substantially higher than the prices that GEHA would have paid absent the illegal conduct alleged.
- 123. Delaying generic competitors in the market place prevented price competition for Lidoderm.
- 124. The prices GEHA paid for Lidoderm therapy were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct. The inflated prices that GEHA paid are traceable to, and the foreseeable result of, the overcharges by Endo.

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IX. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF For Monopolization Under State Law (Asserted Against Endo/Teikoku)

- 125. GEHA hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.
- 126. At all relevant times, Endo/Teikoku possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo/Teikoku possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.
- 127. Through the anticompetitive conduct, as alleged extensively above, Endo/Teikoku willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen in order to exclude competition for Lidoderm, and injured Plaintiff thereby.
- 128. The goal, purpose, and effect of Endo/Teikoku's scheme was to prevent and delay the sale of generic Lidoderm products in the United States at prices significantly below Endo/Teikoku's prices for Lidoderm.
 - 129. Endo/Teikoku's anticompetitive conduct harmed competition as alleged herein.
- 130. By engaging in the foregoing conduct, Endo/Teikoku has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:
 - a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Arizona.
 - b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in California.
 - c. D.C. Code §§ 28-4503, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in the District of Columbia.
 - d. Fla. Stat. §§ 501.201, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Florida.
 - e. Haw. Rev. Stat. § 480-9, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Hawaii.
 - f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Illinois.

- g. Iowa Code § 553.5 *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Iowa.
- h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Massachusetts.
- i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Maine.
- j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Michigan.
- k. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Minnesota.
- 1. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Mississippi.
- m. Neb. Code Ann. §§ 59-802, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Nebraska.
- n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Nevada.
- o. N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Hampshire.
- p. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Mexico.
- q. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in North Carolina.
- r. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with Plaintiff's purchases of Lidoderm and generic Lidoderm in North Dakota.
- s. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in Oregon.
- t. 10 L.P.R.A. § 260, *et seq.*, with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in Puerto Rico.
- u. R.I. Gen. Laws §§ 6-36-5 et seq. (as amended by 2013 R.I. Pub. Laws, ch. 365), with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Rhode Island.
- v. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in South Dakota.
- w. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Vermont.
- x. W.Va. Code §§ 47-18-4, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in West Virginia.

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y.	Wis. Stat. §§ 133.03, et seq., with respect to purchases of Lidoderm and generic
•	Lidoderm in Wisconsin by Plaintiff, in that the actions and transactions alleged
	herein substantially affected and continue to affect the people of Wisconsin, whereby
	Plaintiff paid and substantially higher prices for Lidoderm and generic Lidoderm at
	Wisconsin pharmacies.
~-	-
(ìŀ	EHA has been injured in its business or property by reason of Endo/Teikoku's antitrust

- 131. trust violations. Its injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Lidoderm products for up to thirteen months, and (2) paying higher prices for Lidoderm and generic Lidoderm than it would have paid in the absence of Endo/Teikoku's conduct. These injuries are of the type the laws of the above jurisdictions were designed to prevent, and flow from that which makes Defendants' conduct unlawful.
- 132. GEHA seeks damages and multiple damages as permitted by law for its injuries by Endo/Teikoku's violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF For Attempted Monopolization Under State Law (Asserted against Endo/Teikoku)

- GEHA hereby repeats and incorporates by reference each preceding and succeeding 133. paragraph as though fully set forth herein.
- 134. Through the Reverse Payment Agreement, Endo/Teikoku specifically intended to maintain monopoly power in the relevant market.
- The goal, purpose, and effect of Endo/Teikoku's scheme was to control prices and/or to 135. exclude competition in the relevant market by preventing and delaying the sale of generic Lidoderm products in the United States at prices significantly below Endo/Teikoku's prices for Lidoderm.
- 136. The natural and probable consequence of Endo/Teikoku's anticompetitive conduct, which was intended by them, and plainly foreseeable to them, was to control prices and exclude competition in the relevant market, to the extent it did not succeed.
- 137. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo/Teikoku would succeed in and achieve their goal of maintaining monopoly power in the relevant market.
- By engaging in the foregoing conduct, Endo/Teikoku's has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Arizona.
- b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in California.
- c. D.C. Code §§ 28-4503, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in the District of Columbia.
- d. Fla. Stat. §§ 501.201, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Florida.
- e. Haw. Rev. Stat. § 480-9, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Hawaii.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Illinois.
- g. Iowa Code § 553.5 *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Iowa.
- h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Lidoderm and generic Lidoderm in Massachusetts by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Massachusetts.
- i. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in Maine.
- j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with Plaintiff's purchases of Lidoderm and generic Lidoderm in Michigan.
- k. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Minnesota.
- 1. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Mississippi.
- m. Neb. Code Ann. §§ 59-802, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Nebraska.
- n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Nevada.
- o. N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Hampshire.
- p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in New Mexico.
- q. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in North Carolina.
- r. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in North Dakota.

- s. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Oregon.
- t. 10 L.P.R.A. § 260, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Puerto Rico.
- u. R.I. Gen. Laws §§ 6-36-5 et seq. (as amended by 2013 R.I. Pub. Laws, ch. 365), with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Rhode Island.
- v. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in South Dakota.
- w. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Vermont.
- x. W.Va. Code §§ 47-18-4, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in West Virginia.
- y. Wis. Stat. §§ 133.03, et seq., with respect to purchases of Lidoderm and generic Lidoderm in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid and will continue to pay substantially higher prices for Lidoderm and generic Lidoderm at Wisconsin pharmacies.
- 139. GEHA has been injured in its business or property by reason of Endo/Teikoku's antitrust violations. Its injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Lidoderm products for up to thirteen months, and (2) paying higher prices for Lidoderm and generic Lidoderm than it would have paid in the absence of Endo/Teikoku's conduct. These injuries are of the type the laws of the above jurisdictions were designed to prevent, and flow from that which makes Defendants' conduct unlawful.
- 140. GEHA seeks damages and multiple damages as permitted by law for its injuries by Endo/Teikoku's violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF For Conspiracy to Monopolize Under State Law (Asserted Against All Defendants)

- 141. GEHA hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.
- 142. At all relevant times, Endo/Teikoku possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo/Teikoku possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

143. Through the Reverse Payment Agreement, Endo/Teikoku and Actavis conspired to maintain Endo/Teikoku's monopoly power in the relevant market in order to block and delay market entry of generic Lidoderm.

- 144. The Reverse Payment Agreement (a) allocated 100% of the market for lidocaine patch 5% in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Endo/Teikoku; (b) delayed the availability of generic versions of Lidoderm in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, for up to thirteen months thereby protecting Lidoderm from any generic competition; (c) delayed the entry of Endo/Teikoku's authorized generic until 7½ months after Actavis' entry with a generic Lidoderm product, and allocate 100% of sales for generic lidocaine patch 5% in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Actavis prior to that time; and (d) fixed, at supracompetitive levels, the price at which Plaintiff would pay for lidocaine patch 5%.
- 145. The goal, purpose and/or effect of the Agreement was to maintain and extend Endo/Teikoku's monopoly power in the United States market, including its territories, possessions and the Commonwealth of Puerto Rico, in the market for lidocaine patch 5%, in violation of the state laws enumerated below. The Agreement was intended to and did prevent and/or delay generic competition to Lidoderm and enabled Endo/Teikoku to continue charging supracompetitive prices for Lidoderm without a substantial loss of sales.
- 146. Defendants knowingly and intentionally conspired to maintain and enhance Endo/Teikoku's monopoly power in the relevant market.
- 147. Defendants specifically intended that their Agreement would maintain Endo/Teikoku's monopoly power in the relevant market, and injured Plaintiff thereby.
 - 148. Defendants each committed at least one overt act in furtherance of the conspiracy.
- 149. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain Endo/Teikoku's monopoly power, GEHA paid artificially inflated prices for Lidoderm and generic Lidoderm as described herein, and were harmed as a result.
- 150. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Arizona.
- b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in California.
- c. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in the District of Columbia.
- d. Fla. Stat. §§ 501.201, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Florida.
- e. Haw. Rev. Stat. § 480-9, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Hawaii
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Illinois.
- g. Iowa Code § 553.3 *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Iowa.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Kansas.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to Lidoderm and generic Lidoderm in Massachusetts by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Massachusetts.
- j. Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in Maine.
- k. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Michigan.
- 1. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. §§8.31, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Minnesota.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Mississippi.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Nebraska.
- o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Nevada.
- p. N.H. Rev. Stat. Ann. §§ 356, 356:2, 356:3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Hampshire.
- q. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Mexico.
- r. New York General Business Law § 340, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New York.

- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in North Carolina.
- t. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in North Dakota.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Oregon.
- v. 10 L.P.R.A. § 260, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Puerto Rico.
- w. R.I. Gen. Laws §§ 6-36-7, et seq., (as amended by 2013 R.I. Pub. Laws, ch. 365), with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Rhode Island.
- x. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in South Dakota.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lidoderm and generic Lidoderm in Tennessee by Plaintiff, in that the actions and transactions alleged herein substantially affected Tennessee, whereby Plaintiff paid and will continue to pay substantially higher prices for generic Lidoderm at Tennessee pharmacies.
- z. Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Vermont.
- aa. W.Va. Code §§ 47-18-3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in West Virginia.
- bb. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Lidoderm and generic Lidoderm in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid and will continue to pay substantially higher prices for Lidoderm and generic Lidoderm at Wisconsin pharmacies.
- 151. GEHA has been injured in its business or property by reason of Defendants' antitrust violations. GEHA's injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Lidoderm for up to thirteen months, and (2) paying higher prices for Lidoderm products than it would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above jurisdictions were designed to prevent, and flow from that which makes Defendants' conduct unlawful. GEHA seeks damages and multiple damages as permitted by law for its injuries by Defendants' violations of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF For Conspiracy and Combination in Restraint of Trade Under State Laws (Against All Defendants)

- 152. GEHA hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.
- 153. In 2012, Endo and Actavis entered into the Reverse Payment Agreement to suppress generic competition with Lidoderm and/or its AB generic equivalent. The Reverse Payment Agreement is a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:
 - a. Allocate all sales of Lidoderm in the United States to Endo until at least September, 15, 2013;
 - b. Prevent Actavis from marketing its generic version of Lidoderm in the United States before September 15, 2013;
 - c. Prevent Endo from launching an authorized generic to compete with Actavis' generic Lidoderm for seven and one-half months after Actavis belatedly launched its generic;
 - d. Fix at supra competitive levels the price that GEHA paid for Lidoderm; and
 - e. Fix at supra competitive levels the price that GEHA pays for generic Lidoderm.
 - 154. The Reverse Payment Agreement has harmed GEHA.
- 155. The Reverse Payment Agreement has covered a sufficiently substantial percentage of the relevant market to harm competition.
- 156. The Reverse Payment Agreement is a horizontal market allocation and price fixing agreement between actual and potential competitors and is illegal *per se* under state antitrust laws. Alternatively, GEHA alleges the Reverse Payment Agreement is an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.
- 157. There is and was no legitimate, non-pre-textual, pro-competitive business justification for the Reverse Payment Agreement that outweighs its harmful effect. Even if there were such a justification, the Reverse Payment Agreement is and was broader than necessary to achieve any procompetitive purpose.
- 158. The Defendants' conduct violated the following state antitrust or competition practices laws:

- a. Arizona Rev. Stat §§ 44-1402, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Arizona
- b. Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in California.
- c. D.C. Code Ann. §§ 28-4502, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in the District of Columbia.
- d. Fla. Stat. §§ 501.201, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Florida.
- e. Haw. Rev. Stat. § 480-1, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Hawaii.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Illinois.
- g. Iowa Code § 553.2 *et seq.*, with respect to purchases Plaintiff's purchases of Lidoderm and generic Lidoderm in Iowa.
- h. Kan. Stat. Ann. §§ 50-101, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Kansas.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to Lidoderm and generic Lidoderm in Massachusetts, by Plaintiff who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Massachusetts.
- j. Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Maine.
- k. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Michigan.
- 1. Minn. Stat. §§ 325D.51, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Minnesota.
- m. Miss. Code Ann. §§ 75-21-3, et seq., with to Plaintiff's purchases of Lidoderm and generic Lidoderm in Mississippi.
- n. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Nebraska.
- o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by Plaintiff, who paid substantially higher prices for Lidoderm and generic Lidoderm in actions and transactions occurring substantially within Nevada.
- p. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New Mexico.
- q. New York General Business Law § 340, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in New York.
- r. N.C. Gen. Stat. §§ 75-1, *et eq.*, with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in North Carolina.

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- s. N.D. Cent. Code § 51-08.1-02, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm purchases in North Dakota.
- t. Or. Rev. Stat. §§ 646.705, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Oregon.
- u. 10 L.P.R.A. § 251, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Puerto Rico.
- v. R.I. Gen. Laws §§ 6-36-4 et seq. (as amended by 2013 R.I. Pub. Laws, ch. 365) with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in Rhode Island.
- w. S.D. Codified Laws Ann. § 37-1-3.2, et seq., with respect Plaintiff's purchases of Lidoderm and generic Lidoderm in South Dakota.
- x. Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases of Lidoderm and generic Lidoderm in Tennessee by Plaintiff, in that the actions and transactions alleged herein substantially affected Tennessee, whereby Plaintiff paid substantially higher prices for of Lidoderm and generic Lidoderm at Tennessee pharmacies.
- y. Vt. Stat. Ann. 9, § 2453, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in Vermont.
- z. W.Va. Code §§ 47-18-3, et seq., with respect to Plaintiff's purchases of Lidoderm and generic Lidoderm in West Virginia.
- aa. W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by Plaintiff:
- bb. Wis. Stat. § 133.03, et seq., with respect to purchases of Lidoderm and generic Lidoderm in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Lidoderm and generic Lidoderm at Wisconsin pharmacies.
- 159. GEHA purchased Lidoderm and/or its AB-rated generic equivalent from retail pharmacies during the relevant time period.
- 160. GEHA has been injured in its business or property by Defendants' antitrust violations. GEHA's injuries consist of (1) being denied the opportunity to purchase lower-priced generic Lidoderm before September 16, 2013, and (2) paying higher prices for Lidoderm and its AB-related bioequivalents than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.
- 161. GEHA seeks damages and multiple damages as permitted by law for the injuries they suffered because of the Defendants' anticompetitive conduct.

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62. Defendants are jointly and severally liable for all damages suffered by GEHA.

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FIFTH CLAIM FOR RELIEF Unfair and Deceptive Practices Under State Laws

(Thirty-Seven States and the District of Columbia)
(Against All Defendants)

- 163. GEHA re-alleges the preceding paragraphs as though set forth herein.
- 164. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed by, among other things, (a) wrongfully conducting baseless litigation to trigger the automatic 30-month stay prohibiting FDA from granting final approval permitting Actavis to market its less-expensive authorized generic version of Lidoderm; (b) entering into the Reverse Payment Agreement whereby Endo agreed to pay Actavis in exchange for Actavis' commitment to postpone marketing its generic version of Lidoderm; (c) compensating Actavis at least \$96 million in free product under the Reverse Payment Agreement; and (b) agreeing not to compete against Actavis with Endo's own authorized generic Lidoderm. As a result of the Reverse Payment Agreement, Actavis did, in fact, delay marketing its less expensive Lidoderm, despite having FDA approval to do so.
- 165. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, GEHA was deprived of the opportunity to purchase a generic version of Lidoderm before September 16, 2013, and were forced to pay higher prices for brand name Lidoderm.
- 166. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*
- 167. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.
- 168. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.
- 169. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §17200, *et seq*.

- 170. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat § 6-1-105, *et seq*.
- 171. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq*.
- 172. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.
- 173. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.
- 174. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.
- 175. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*.
- 176. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code §§ 24-5-0.5-1, *et seq*.
- 177. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq*.
- 178. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. Ann. § 51:1401, *et seq*.
- 179. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*.
- 180. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.
- 181. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq*.
- 182. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325D.43, *et. seq.*, Minn. Stat. § 325F.69, *et seq.*, and Minn. Stat. § 8.31, *et seq.*

violation of S.D. Code Laws § 37-24-1, et seq.

- 208. Defendant Actavis has benefitted from the acts alleged in this Complaint to the extent of the payments (at least \$96 million in free product in total) that it has received under the Reverse Payment Agreement. The funds for such payments by the Endo Defendants derived from GEHA's overpayments for Lidoderm.
- 209. GEHA has conferred an economic benefit upon the Defendants in the nature of revenue resulting from payments made during the pendency of the antitrust conspiracy, to GEHA's detriment.
- 210. The economic benefit of payments made by GEHA during the conspiracy is a direct and proximate result of Defendants' anticompetitive behavior restricting competition as set forth above.
- 211. The benefit held by the Defendants rightfully belongs to GEHA, as GEHA paid these inequitable sums that flowed to Defendants as profits during the relevant time period, when Defendants used illicit and inequitable measures to delay generic entry into the market.
- 212. It would be inequitable for Defendant Actavis to retain any of the proceeds of the Reverse Payment Agreement.
- 213. It would be inequitable for the Endo Defendants to be permitted to retain any of the revenue generated from GEHA's payments for Lidoderm derived from their unfair and unconscionable methods, acts, and trade practices, including, but not limited to, the Reverse Payment Agreement and the acts alleged herein, designed to delay introduction by Actavis and others of generic bioequivalents to Lidoderm.
- 214. It would be futile for GEHA to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the illicit and inequitable benefits they received from GEHA.
- 215. Defendants are aware of and appreciate the benefits they obtained inequitably that came from GEHA.
- 216. Defendants should be compelled to disgorge all incremental proceeds they obtained inequitably as a result of the unjust conduct alleged herein in a common fund for the benefit of GEHA.
- 217. A constructive trust should be imposed upon all sums the Defendants obtained inequitably that are traceable to GEHA.
 - 218. GEHA has no adequate remedy at law.

X. **DEMAND FOR JUDGMENT** 1 2 WHEREFORE, GEHA respectfully prays that the Court: 3 A. Enter Judgment against Defendants jointly and severally in favor of GEHA; 4 B. Award GEHA actual damages and multiple damages or punitive damages where 5 available by law in an amount to be determined at trial; C. Disgorge from Defendants all illicit and inequitable sums they received due to their 6 7 improper conduct and establish a constructive trust over these monies; 8 D. Award GEHA its costs of suit, including reasonable attorneys' fees as provided by law; 9 E. Grant any such other further relief to which GEHA may be entitled and/or is necessary to correct the anticompetitive effects caused by the unlawful conduct of Defendants and as the Court 10 11 deems just and/or equitable. /// 12 /// 13 /// 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

1	XI.	JURY DEMAND		
2		Pursuant to Rule 38 of the Federal Rules of Civil Procedure, GEHA demands a trial by jury on		
3	all issu	all issues so triable.		
4		Dated: June 13, 2014		
5		San Francisco, California		
6			BERMAN DEVALERIO	
7				
8			By: /s/ Todd A. Seaver	
9			Todd A. Seaver	
10			Joseph J. Tabacco, Jr. Sarah Khorasanee McGrath	
			One California St., Suite 900	
11			San Francisco, CA 94111 Tel.: 415- 433-3200	
12			Fax: 415- 433-6382 Email: jtabacco@bermandevalerio.com	
13			tseaver@bermandevalerio.com skmcgrath @bermandevalerio.com	
14			LOWEY DANNENBERG COHEN	
15			& HART, P.C. Barbara Hart	
16			Peter D. St. Phillip Uriel Rabinovitz	
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